Review Comments on 2009 CDC Draft of
"Guidelines for the Prevention of Intravascular Catheter-Related Infections"

These comments are from the Clinical Practice Committee and select content expert members of the American Society for Parenteral and Enteral Nutrition. Our comments are organized as:

Level One: Concepts and Content Issues

Level Two: Format, style or grammar issues

Level One: Concept and content issues
General Comments

Comment
The following Working Group members (SCCM, ACCP, ATS and IDSA) are also members who have either endorsed or are using GRADE (Grading of Recommendations Assessment, Development and Evaluation) [http://www.gradeworkinggroup.org/society/index.htm] Other GRADE groups include WHO, AHRQ and The Cochrane Collaboration. GRADE is becoming the international norm for the grading of evidence. This paper's grading system (see p3) neither contains an objective description of the levels of evidence nor a reference citation. Categories IA and IB are both labeled "strongly recommended for implementation" but are based on disparate and non-transparent, objective evidence. Recommend that the grading system be reviewed and revised to promote good practice guidelines that include: clarity, compatibility, clear rationales or justifications, practicality, and transparency.
Consider a small glossary or table summarizing the difference between catheter-related bloodstream infection, catheter-associated bloodstream infection, etc. Also used some different terms throughout--central line associated bloodstream infection, CVC-associated blood stream infection, in addition to CABSI and CRBSI. This is very confusing.
No commentary on using a dedicated lumen for parenteral nutrition, which was addressed in the 2002 guidelines. Was this omission deliberate?
The draft should only use FDA/USP/USAN generic drug names in the text. Abbreviations, slang or stem drug names should not be used. See ISMP (http://www.ismp.org/Tools/errorproneabbreviations.pdf) and The Joint Commission (http://www.jointcommission.org/PatientSafety/DoNotUseList/) Examples: "lipid emulsion" should be "IV fat emulsion", "glucose" (IV product) should be "dextrose" (IV product)
USP <797> Pharmaceutical Compounding—Sterile Preparations details the procedures and requirements for compounding sterile parenteral preparations and sets standards that are applicable to all practice settings in which sterile preparations are compounded. Since the standards became official,

they have been widely adopted, are enforced by FDA, many state boards of pharmacy or departments of health, and may be surveyable by accreditation organizations (e.g., The Joint Commission). It is highly recommended that USP <797> be reviewed for inclusion throughout this paper. USP <797> would be a Category IC Recommendation based on the current grading system. Consider appointing a pharmacist to this working group for the next revision.
There is no mention of in-line filters although they are still used in administration of Parenteral Nutrition with a strong recommendation by the FDA. Food and Drug Administration. Safety alert: hazards of precipitation associated with parenteral nutrition. *Am J Hosp Pharm.* 1994;51:1427–1428.
It would be helpful if a comment would be made about the optimal tip placement for CVC (especially for infusion of hyperosmolar solutions-distal SVC? CA junction?) as thrombosis and infection are associated. AND use of PICC (upper extremity insertion site) as a preferred catheter/site based on the density of skin flora in comparison to chest / neck / groin.
The recommendation for use of the subclavian route whenever possible conflicts with the recommendation for ultrasound visualization. One cannot easily visualize the subclavian vein using the generally available bedside ultrasound instruments, and placement of catheters through the subclavian route is not generally done using ultrasound. The jugular route is normally used for safety during insertion, using ultrasound.
There is little guidance for parenteral nutrition administration, other than that lipids should be given within 24 hours (or maybe 12 hours if given alone). There is virtually no guidance offered for the use of chronic central access for long-term home PN.
One observation: the gown, glove, mask, and sterile barrier approach to venous and arterial cannulation is not usually used by anesthesiologists, who are the ones who do most of these in the OR. Implementation of these practices will require a considerable change in their practice, as well as an increase in the length of time required with patients under anesthesia.

Specific Comments

Draft Location	**Comment**
Lines 276-279	Under Background, there is no mention of pharmacy personnel in the preparation of compounded sterile products using aseptic technique despite on page 10, line 219 mentioning infusate contamination.
Lines 483-486	Would like a comment on the use of the BioPatch with antimicrobial CVCs.
Lines 547-550	A case could be made for the use of sutureless securement devices for other CVCs in addition to PICCs (temporary subclavian & jugular); products are available.
Line 707	Would like clarification if this applies to adults, children, both—what? Also, it does not address neonates with long term catheters and they all seem to have multiple infections. The actual document does address pediatric patients but the recommendation does not.
Lines 1044,1047,1061,1153, 1155,1589,1592,1635,1637	the use of "lipid" emulsions is not what the commercially available products state on the U.S. market as they are "fat" emulsions
Lines 1048,1593	Similarly, the use of "glucose" is not what is used in the U.S. for commercial IV fluids, but "dextrose"

Line 1059	"…if fluids that enhance microbial growth (e.g., parenteral nutrition…." assuming they are referring to PN when they are actually more likely making a statement about fat emulsions alone (the reference from Raad was at an institution that uses exclusively dextrose and amino acids infusions while fat emulsion is infused alone – this was not specified in his study either) as the references also included IL-2 infusions. They may want to make a statement about how PN formulations actually are deterrents for microbial growth (especially when refrigerated) except for *Staphylococcus* or *Candida* species at room and body temperature (***Didier ME, et al.* JPEN 1998;22:291-6**).
Lines 1134-5	Consider changing to "Compound all parenteral fluids according to USP <797> Pharmaceutical Compounding—Sterile Preparations" (change reference to USP chapter <797>)
Lines 1137, 1619	This document does not use the correct terminology about beyond use date given most compounded sterile products are prepared in the facility, not by a manufacturer. On page 51, recommendation 9 (line 1149 on page 51 and line 1631 on page 75) once again uses the manufacturer's stated expiration period instead of the USP Chapter 797 designations of low, medium or high categories of risk and their respective time periods for beyond use dating.
Lines 1153-1154	Change statement to the following for accuracy: "Complete the infusion of parenteral nutrition formulations that includes IV fat emulsion (e.g., 3-in-1 formulation) within 24 hours of hanging the formulation." [Note: once a preparation contains IV fat emulsion, it can no longer be referred to as a solution]
Lines 1155-1157	The Workgroup needs to revisit this Recommendation. All three of the cited references are in-vitro, microbial growth studies; none are infection control outcome studies. What is the infection control outcome evidence pertaining to the 12 hour infusion time? What is the infection control outcome evidence to suggest that one single, unopened container of IV fat emulsion spiked with a single, new administration set and infused for one day would not be clinically appropriate?. If the Workgroup elects to maintain the current draft statement, then the grade should be changed to Category II based solely on the in-vitro evidence provided. [Note: the infusion scenario of IV fat emulsion is unlike the multiple containers / multiple manipulations per day of propofol.]
Line 1160	States "No recommendation can be made for the hang time of other parenteral fluids." However, USP <797> Pharmaceutical Compounding—Sterile Preparations does include standards for the Beyond Use Dating of a variety of compounded sterile preparations. Recommend that the USP <797> Beyond Use Dating guidelines be mentioned and cited in this section of this paper.
Lines 1246-1247, Table 1	Change Peripheral Venous Catheters, Entry Site to "inserted into subcutaneous vein"

Lines 1256-1258, Table 1	Are all midline catheters inserted in the antecubital fossa?? Insertion site could be proximal or distal to the fossa and still enter the basilica or cephalic vein? Would avoid the fossa so that dressing adherence could be better attained by avoiding stress on the dressing when the arm bends.

Level 2: Format, style or grammar issues

General Comment

Number spacing; e.g., 1000 vs. 1,000. See the 10th edition of the AMA Manual of Style, p793-794. "By SI convention, the decimal point is the only punctuation mark used in numerals. The SI does not use commas in numbers…" Please review all text for use of numbers of 4 digits or greater.

Specific Comment

Draft Location	Comment
Line 65	consider word revision to. reporting rates of compliance with all components of the bundle as benchmarks for
Line 93	the term reducing seems awkward and probably could be word smithed for clarity.
Line 137	consider word revision to. surveillance definition for BSIs, including central-line associated BSIs, is when
Line 193	insert a period. prevention efforts [18]. For gram negative rods, antimicrobial resistance to third
Line 199	this is the first time NNIS is used in the document. Should word out in full. National Nosocomial Infections Surveillance (NNIS)
Lines 202-205	What about neonates between 750-2500gm and CVC infection rates? Should reference Table 3. The last sentence in this paragraph seems dangling and needs completion
Line 203	compare this line with the format of lines 181 and 182. <750 gram and >2500 gram
Line 208	consider word revision: by coagulase-negative staphylococci. From 1992-1999, these bacteria accounted for
Line 229	consider word revision. Change "on the other hand" to conversely
Line 252	consider defining the word slime. Or changing it to biofilm
Lines 257 to 258	consider rewording section to read easier
Lines 271 to 274	consider rewording section to read easier
Line 324	consider word revision to: risk for phlebitis in children does not increase with the duration of catheterization.
Line 327	consider word revision: change the word Authorities to Experts or Expert opinion or Experienced Clinicians
Line 412	should read CRBSI not CR-BSI

Line 431	add a period to the end of unresolved issue.
Line 495	should read substantial differences exist in either the incidence of catheter site colonization or phlebitis
Line 515	should read. A randomized controlled study of 140 children using polyurethane or a chlorhexidine
Line 557	securement is misspelled
Line 881	should read. guidewire, in combination with antibiotic therapy, is an alternative salvage strategy
Line 1137	consider: if the manufacturer expiration date or assigned beyond use date has passed.
Line 1142	consider: if multidose vials are used, store the multidose vial as recommended by the manufacturer
Lines 1149-1150	consider: 9. All multidose vials should be dated when first used. The product should not be used beyond the assigned beyond use date which may be the manufacturers stated expiration period.
Lines 1243-1306	Table 1 was very difficult to read--seems like there were some formatting issues there Change all lengths to cm